

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**75-311**

**APPROVAL LETTER**

JAN 31 2001

TEVA Pharmaceuticals USA  
Attention: Philip Erickson  
1090 Horsham Road  
PO Box 1090  
North Wales, PA 19454-1090

Dear Sir:

This is in reference to your abbreviated new drug application dated December 29, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Famotidine Tablets USP, 20 mg and 40 mg.

Reference is made to our tentative approval letter dated October 15, 1998, and to your amendments dated October 4, November 22 and December 7, 2000.

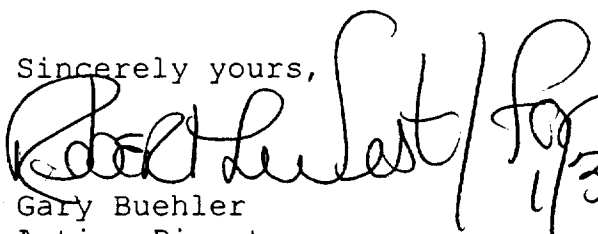
Our October 15, 1998, tentative approval letter informed you that final approval of this application could not be made effective pursuant to 21 U.S.C. 355 (j)(5)(B)(ii) of the Act until U.S. Patent No. 4,283,408 had expired. This patent was issued to the holder of the reference listed drug product (RLD), Pepcid Tablets of Merck Research Laboratories. As noted in the current edition of the Agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", the "Orange Book", this period was scheduled to expire on October 15, 2000. However, Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) created section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits the holder of the new drug application (NDA) for the RLD to obtain an additional six months of marketing exclusivity (pediatric exclusivity). To be awarded this exclusivity, the NDA holder must abide by the terms of the statute and submit data previously requested by the agency relating to the use of the drug product in the pediatric population. Merck has submitted data to the agency to support the use of famotidine in the pediatric population. The agency's Pediatric Exclusivity Board has reviewed the data.

As a result, the agency has awarded Merck an additional 6-months of pediatric exclusivity. This additional 6-months will effectively extend the expiration of the '408 patent until April 15, 2001. Therefore, final approval of this application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(D) of the Act until April 15, 2001.

We refer you to our October 15, 1998, tentative approval letter regarding reactivation of this application in anticipation of final approval. With the exception of the October 15, 2000 date, the comments provided therein remain current.

If you have questions concerning the status of this application, please contact Kassandra Sherrod, R.Ph., Project Manager, at (301) 827-5849.

Sincerely yours,

 1/31/2001

Gary Buehler  
Acting Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research